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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,993

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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

02/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/624,993	Applicant(s) SUKHISHVILI ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6 pages</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

Applicant's election of Group III and the species where the claimed process requires adjusting the pH of the film to create the first excess charge first, then creating a second excess charge opposite to the first excess charge, then contacting the film with the macromolecule solution and repeating the sequence, such that a bioactive agent is the macromolecule, in the reply filed on November 27, 2007 is acknowledged. Upon further consideration, the examiner has withdrawn the original requirement to also elect a specific polymer forming the multilayer film and specific bioactive agent. The elected invention and species read on claims 15-16, 18, and 20. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)). The restriction is deemed proper and thereby made FINAL.

Claims 1-14, 17, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries set forth by *Graham V. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sukhishvili et al. (Journal of the American Chemical Society 2000 122:9550-9551) in view of Decher et al. (Macromolecules 1993 26:5396-5399).

Sukhishvili et al. teach a process of reversibly producing a layered polymer film, such that the layers can be selectively removed (see title and column 1 paragraph 1 lines 7-11; instant claim 15). Additionally, Sukhishvili et al. also teach that these films have applications in medicine and pharmaceuticals, such as in drug release (see page 9550 column 1 paragraph 1 lines 12-14 and page 9551 column 1 paragraph 1 line-column 1; instant claim 15) The layered structure is taught to be built from the sequential addition of poly-acid or poly-base layer to a substrate; thus like acid and base, both of these types of polymers can be modulated between

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an electrostatically charged and uncharged state (see column 1 paragraph 2 lines 2-3; instant claim 1). Further Sukhashvili et al. also teach that polymer systems other than those exemplified could also be used in this process and suggest synthetic polymeric nucleotides (bioactive macromolecules) in particular (see page 9550 column 1 paragraph 2 lines 7-13; instant claim 20). Decher et al. teach that macromolecules such as DNA, with its negative charge, can also be utilized in such layered films based upon alternating layers of oppositely charged polymers (see page 5997 column 1 paragraph 2; instant claim 20). In the discussion of the construction of the layered system, Sukhishvili et al. teach that the layered structure is built at a single (first) pH (see figure 1 caption lines 1-2 and 21-22; instant claim 15). Later when the layered film was treated with a solution of a differing pH, charge was introduced into the layer (first excess charge) along one of the polymers causing the layers to separate due to electrostatic repulsion (see page 9550 column 2 paragraph 3; instant claim 15). The repulsion pushes the remaining portion of the system toward a balanced amount of charge. Thus in view of the teachings of Sukhishvili et al. in view of Decher et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to practice the process of instant claims 15 and 20. Therefore claims 15 and 20 are obvious over Sukhishvili et al. in view of Decher et al.

Claims 15, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sukhishvili et al. in view of Decher et al. and Hiller et al (USPGPub No. 2003/0215626).

Sukhishvili et al. and Decher et al. made obvious the process of claims 15 and 20 (see **Claim Rejections - 35 USC § 103** for claims 15 and 20). Hiller et al. teach a very similar process and set of polymers (e.g. poly acrylic acid) to construct a multilayered polyelectrolyte film (see Hiller et al. paragraph 29 lines 9-10 and 30; Sukhishvili et al. page 9550 column 1 paragraph 2 lines 2-5). Both Hiller et al. and Sukhishvili et al. teach a change in layer behavior

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that is controlled by pH (producing a change in the ionization state of polymer in the layers), removal of layers in the case of Sukhishvili et al. and porosity in the case of Hiller et al. (see Sukhishvili et al. page 9550 column 2 paragraph 3; Hiller et al paragraph 34 lines 1-8). Further Hiller et al. teach that the pH induced porosity can be cycled (film made porous, then non-porous, repeatedly) within the multi-layered structures (see paragraph 47 lines 1-7; instant claim 16). Since it is possible to cycle the ionization within such multilayered structures, it would have been obvious to one of ordinary skill in the art at the time of the invention to practice the process of instant claim 15 and then cycle the ionization (or charge balance) in the layer, by altering the pH, such that the layered structure could be reversibly built again. In addition, since common charge prompted the repulsion responsible for the layer removal, it would have been obvious at the time of the invention to one of ordinary skill in the art to induce an opposite charge in the remaining structure to rebuild the layers. Furthermore, according to MPEP 2144.04, the duplication of parts, or steps in the case of a process, does not impart any patentable significance unless some expected result is produced. [see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a “web” which lies in the joint, and a plurality of “ribs” projecting outwardly from each side of the web into one of the adjacent concrete slabs. The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).] Therefore claims 15, 16, and 18 are obvious over Sukhishvili et al., Decher et al, and Hiller et al.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615

Caralynne Helm
Examiner
Art Unit 1615

CH